(a) the pharmaceutical composition comprises an oral contraceptive for preventing pregnancy in a subject, and folic acid in an amount sufficient to treat or prevent cervical displasia or cervical carcinoma which (i) afflicts subjects for whom the oral contraceptive is indicated at a higher-than-normal incidence, (ii) results from folic acid deficiency, and (iii) is treatable or preventable by folic acid administration, and

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(b) the subject is from a population whose members are afflicted with, or are predisposed to become afflicted with, cervical displasia or cervical carcinoma at a higher than normal incidence, the disorder being treatable or preventable by folic acid administration.

Please add the following new claims:

2 22. (New) The method of claim 21, wherein the composition comprises from about 25 μg to about 1 g of folic acid.

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3 23. (New) The method of claim 22, wherein the composition comprises about 400 μg of folic acid.

REMARKS

Prior to amendment claim 21 was the sole claim pending in this application. Claim 21 has been amended. New claims 22 and 23 have been added.

Claims 21 has been rejected under 35 U.S.C. § 112, first paragraph, it being the Examiner's position that the disclosure fails to teach one skilled in the art how to treat or prevent the disorders enumerated in the claims. Claim 21 has been amended to define more particularly what applicants regard as the invention. In particular, claim 21 has been amended to state that the composition administered according to the claimed method comprises folic acid in an amount sufficient to treat or prevent a disorder which (i) afflicts subjects for whom the oral contraceptive is indicated at a higher-than-normal incidence, (ii) results from folic acid deficiency, and (iii) is treatable or preventable by folic acid administration.

The fact that cervical displasia and cervical carcinoma can result from insufficient folic acid levels is well documented in the art, as discussed at pages 3-5 of the specification.